34 Year Overview of Patient Information and FDA

- 1968 - First prescription medication to require consumer-oriented written information, isoproterenol inhalation
- 1969 - APhA changes code of ethics to allow pharmacist counseling
- 1970 - FDA requires consumer information with estrogen containing products

FDA's PPI Proposed Rule

- 1979 - FDA proposed a rule to distribute FDA approved PPI's
- The rule covered 10 drug class initially
- Medicine and Pharmacy protested rule
- 1982 - FDA withdraws PPI rule
- NCPIE formed to promote private sector initiative

3874B1_01_OVERVIEW PATIENT INFO

1991 - FDA Revisits Patient Information

- Only 32% of patients getting any written information from private sector - FDA survey
- Written information is very variable
- FDA continued to encourage voluntary effort of private sector through articles and speeches

August 24, 1995

- FDA publishes Medication Guide Proposed Rule for drugs with serious and significant side effects
- Proposal sets distribution targets of 75% and 95% by 2000 and 2006 for private sector
- FDA proposes criteria to judge written information as being useful

FDA Telephone Surveys of Patients About Written Information Received with New Prescriptions

Percent of Patients Who Were Given Written Information at the MD's Office/ Pharmacy

		MD Office				Pharmacy			
YEAR		1992	1994	1996	1998	1992	1994	1996	1998
% of All Respondents Given Written Information		14	15	16	16	32	59	71	74
% Type of Information Received (of those who got information)	Brochure	42	49	50	57	33	28	29	38
	Instruction Sheet	77	71	66	78	60	82	85	85
	Sticker on medicine container	N/a	N/a	N/a	N/a	74	78	78	83

*These %'s do not reflect the quality or "usefulness" of the information, as no content evaluation was conducted.

1996 Events

- February 14 and 15 - FDA convenes workshop on the medication guide proposal, specifically related to defining useful information
- August 29 - Congress passed and President signed Public Law 104-180 limiting FDA regulation of private sector information unless goals are not met

Public Law 104-180

- Directs Secretary of HHS to facilitate development of a long-range action plan that meets stated goals through private sector efforts
- Gives private sector opportunity to meet distribution and quality standards of plan
- Codifies FDA's distribution and quality goals of 75% by 2000 and 95% by 2006

TITLE VI

RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

SALARIES AND EXPENSES

[redacted] purchase of passenger motor vehicles, for rental of space in the District of Columbia or elsewhere; and for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; $907,499,000, of which not to exceed $87,528,000 in fees pursuant to section 736 of the Federal Food, Drug, and Cosmetic Act may be credited to this appropriation and remain available until expended: *Provided,* That fees derived from applications received during fiscal year 1997 shall be subject to the fiscal year 1997 limitation: *Provided further,* That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701.

In addition, fees pursuant to section 354 of the Public Health Service Act may be credited to this account, to remain available until expended.

In addition, fees pursuant to section 801 of the Federal Food, [redacted]

GENERAL PROVISIONS

SEC. 601. EFFECTIVE MEDICATION GUIDES.— 21 USC 353 note.

(a) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, the Secretary of the Department of Health and Human Services shall request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule of the Food and Drug Administration on "Prescription Drug Product Labeling: Medication Guide Requirements" (60 Fed. Reg. 44182; relating to the provision of oral and written prescription information to consumers).

(b) GOALS.—Goals consistent with the proposed rule described in subsection (a) are the distribution of useful written information to 75 percent of individuals receiving new precriptions by the year 2000 and to 95 percent by the year 2006.

(c) PLAN.—The plan described in subsection (a) shall—

(1) identify the plan goals;

(2) assess the effectiveness of the current private-sector approaches used to provide oral and written prescription information to consumers;

Guidelines.

(3) develop guidelines for providing effective oral and written prescription information consistent with the findings of any such assessment;

(4) contain elements necessary to ensure the transmittal of useful information to the consuming public, including being scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product.

(5) develop a mechanism to assess periodically the quality of the oral and written prescription information and the frequency with which the information is provided to consumers; and

(6) provide for compliance with relevant State board regulations.

(d) LIMITATION ON THE AUTHORITY OF THE SECRETARY.—The Secretary of the Department of Health and Human Services shall have no authority to implement the proposed rule described in subsection (a), or to develop any similar regulation, policy statement, or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if, (1) not later than 120 days after the date of enactment of this Act, the national organizations described in subsection (a) develop and submit to the Secretary for Health and Human Services a comprehensive, long-range action plan (as described in subsection (a)) which shall be acceptable to the Secretary of Health and Human Services; (2) the aforementioned plan is submitted to the Secretary of Health and Human Services for review and acceptance: *Provided,* That the Secretary shall give due consideration to the submitted plan and that any such acceptance shall not be arbitrarily withheld; and (3) the implementation of (a) a plan accepted by the Secretary commences within 30 days of the Secretary's acceptance of such plan, or (b) the plan submitted to the Secretary commences within 60 days of the submission of such plan if the Secretary fails to take any action on the plan within 30 days of the submission of the plan. The Secretary shall accept, reject or suggest modifications to the plan submitted within 30 days of its submission. The Secretary may confer with and assist private parties in the development of the plan described in subsections (a) and (b).

(e) SECRETARY REVIEW.—Not later than January 1, 2001, the Secretary of the Department of Health and Human Services shall review the status of private-sector initiatives designed to achieve the goals of the plan described in subsection (a), and if such goals are not achieved, the limitation in subsection (d) shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals.

[redacted]

SEC. 603. AMENDMENTS [redacted] DRUG, AND COSMETIC ACT.—

21 USC 381.

[redacted]

Keystone Center

- Secretary immediately contracts with the Keystone Center to facilitate report development by stakeholders
- Keystone is a non-profit consensus-building alternate dispute resolution organization
- Statute gave 120 days to develop a stakeholder action plan
- Keystone selects 34 organizations

Action Plan

- Collaboratively developed plan accepted by the Secretary in January 1997
- Plan endorsed conceptual criteria specified in the public law for determining usefulness
- Consistent with the public law, the plan called for periodic assessment of the quality of written information

1998 FDA Interim Assessment

- FDA contracted with NABP to do an interim pilot assessment
- State Boards of Pharmacy would arrange for collecting medication information materials given with new prescriptions
- Contract called for development of evaluation materials to assess usefulness of information

1998 - FDA Publishes Final Medication Guide Rule

- December 1 - Final Rule published
- Rule estimates 5-10 products per year could have a Medication Guide
- Medication Guide reserved for drugs with serious and significant side effects

February 2000 Public Meeting

- Results of interim assessment shared with stakeholders
- FDA gets feedback on draft scoring instrument from stakeholders
- FDA announces plans for end of year 2000 study called for in Public Law 104-180

June 2000 FDA Begins Plan for First Assessment

- Funding secured
- FDA renews contract with NABP and University of Wisconsin Pharmacy School for evaluation phase
- 384 pharmacies selected throughout virtually every state and a professional shopping service selected to buy four prescription drugs and collect data

Current Status of Useful Written Prescription Drug Information for Patients
Public Workshop

February 29-March 1, 2000

DoubleTree Hotel, Rockville, MD

AGENDA

Day 1

1:00 – 1:30	*Moderator*	Nancy M. Ostrove, Ph.D. FDA, CDER, Branch Chief Division of Drug Marketing, Advertising, and Communications
	Welcome	Nancy Smith, Ph.D. FDA, CDER, Director Office of Training and Communications
	Why Are We Here	Thomas J. McGinnis, R.Ph. FDA, Office of Policy Director of Pharmacy Affairs
1:30 – 1:45	*History of Recent Private-Sector Information Efforts*	Judith A. O'Brien Associate Facilitator The Keystone Center
1:45 – 2:00	*Background on the Patient Information Project*	Karen Oster Assistant to the Executive Director National Association of Boards of Pharmacy
2:00 – 3:00	*1999 Patient Information Assessment*	Bonnie Svarstad, Ph.D. Professor of Pharmacy University of Wisconsin
3:00 –3:15	**BREAK**	
3:15 – 5:00	*Assessment, cont.*	Bonnie Svarstad, Ph.D.
5:00 – 5:30	*Questions from the audience*	Nancy M. Ostrove, Ph.D.

Current Status of Useful Written Prescription Drug Information for Patients
Public Workshop

February 29-March 1, 2000

DoubleTree Hotel, Rockville, MD

AGENDA

DAY 2

8:30 – 9:00	***Continental Breakfast***	
9:00 – 9:30	***Welcome***	Nancy M. Ostrove, Ph.D.
	Opening Remarks	Janet Woodcock, M.D. Director, Center for Drug Evaluation and Research
	Small Group Assignments	Nancy M. Ostrove, Ph.D.
9:30 – 9:45	**Move to Breakout Rooms**	
9:45 – 12:00	***Breakout Sessions***	
12:00 – 1:15	**Lunch**	
1:15 – 2:45	***Results from Breakout Sessions***	Workshop Facilitators
2:45 – 3:00	***Closing Remarks***	Nancy Ostrove, Ph.D.

Adjourn

FDA is seeking comments on several issues:

1. What should be the minimum standard or threshold that must be met for written information to be considered useful?

2. Should certain criteria derived from the Action Plan recommendations be given more weight than others? If so, which criteria should be weighted more strongly and why?

3 Are the evaluation forms an accurate translation of the Action Plan's criteria?

4. Should the assessment include additional criteria or types of information, and, if so, what?

5. Should there be a more detailed assessment of factors affecting readability and legibility for consumers (e.g., type size, style, spacing, contrast)?

6. Should the evaluation panel include consumers with varying educational backgrounds? If so, how should they be involved in the evaluation process?

7. This report collected patient information from U.S. retail pharmacies. Are there ways to expand sampling to include mail-order or other non-retail pharmacies?

2001 National Evaluation

- Same evaluation methods as 1999 pilot study
- National Association of Boards of Pharmacy (NAPB) contract
- Sampled > 1300 CMI brochures
- Brochures evaluated by expert panel
    - Pharmacy
    - Medical Information
    - Drug Information

2001 National Evaluation

Endpoints

- Penetration
- Usefulness of each material via eight criteria

Methods

- 384 representative "brick and mortar" pharmacies
- Shopper with standardized scenario presented four prescriptions

Results-Penetration

Frequency of Distribution of Written Information

- Atenolol: 89.6%
- Atorvastatin (Lipitor) 89.3%
- Glyburide 88.8%
- Nitroglycerin 88.3%

Results-Usefulness

- Usefulness defined by multiple stakeholders at Keystone
- Eight criteria
- Each criterion rated by objective subcriteria
- Scored to common scale of 0 to 100% (best)
- Scores categorized into levels 1 to 5 (best)

Scoring Categories

Levels of Compliance

Level	Point Range %
5	80-100
4	60-79
3	40-59
2	20-39
1	0-19
0	no information given out

Eight Criteria for Useful Medication Information

1. Drug Names, indications for use
2. Contraindications, what to do
3. How to use, monitor, and get most benefit for drug
4. Precautions, how to avoid harm

Eight Criteria for Useful Medication Information

5. Serious or frequent adverse reactions, what to do
6. General information, encouragement to ask questions
7. Scientifically accurate, not promotional, and up-to-date
8. Comprehensible (6-8th grade), legible

Ratings of Usefulness, All Criteria Combined

Drug	Levels 1-2 (0-39%)	Level 3 (40-59%)	Level 4 (60-79%)
Atenolol	13.0	56.5	20.1
Glyburide	14.7	48.7	24.5
Atorvastatin	13.6	58.9	16.9
Nitroglycerin	13.5	33.1	41.7

Results for Each Criterion

Best Performance

Criterion 7: Scientifically Accurate
Non-promotional
Up-to-Date

- Level 5 (highest): 95% of materials

Middle Range Scores

Criterion 1: Drug Name, indication

- Level 5: 32%
- Level 1: 12%, Level 2: 16%

Criterion 3: Directions for how to use, monitor, and get most benefit

- Level 5: 19%
- Level 4: 47%

Low Scores

Criterion 5: Serious/frequent ADRs, what to do

- Level 5: 13%
- Level 1: 15%; Level 2: 33%

Criterion 6: General information, ask questions

- Level 5: 13%
- Level 1: 32%; Level 2: 25%

Lowest Scores

Criterion 8: Readable, legible

- Level 5: 1%
- Level 2: 24%; Level 3: 57%

Criterion 2: Contraindications, what to do

- Level 5: 5%
- Level 1: 15%, Level 2: 36%

Criterion 4: Precautions, how to avoid harm

- Level 5: 7%
- Level 1: 22%

Conclusions (1)

- Distribution of CMI over 85%
- Usefulness of CMI variable
- Best performance:
    - Scientific accuracy, non-promotional
    - Pregnancy contraindication

Conclusions (2)

Completeness of CMI is poor and variable

Worst: Communication and Risk Information

- Contraindication and what to do
- Precautions and how to avoid harm
- Readability

Poor: Communicating How to Get Most benefit

- ADRs and what to do
- Directions for use and monitoring
- Encouragement and ask questions

Consumer Information Flow